REMARKS/ARGUMENTS

Claims 1, 5-21, 24-43 and 45-61 are under examination in the application. Claims 4, 22-23, 44 and 62-80 have been cancelled. The Office Action mailed on December 8, 2006, includes the following objections and rejections:

1. Claims 1, 9, 12-22, 28-30 and 33-39 are rejected under 35 U.S.C. § 102;
2. Claims 1, 9, 11 and 18 are rejected under 35 U.S.C. § 102; and
3. Claims 1, 5-22, 24-43 and 45-61 are rejected under 35 U.S.C. § 103(a).

Claim Objections and Rejection under 35 U.S.C. §112, Second Paragraph

Applicants have cancelled and/or amended the claims to address each of the grounds for claim objection or rejection. Applicants respectfully request the withdrawal of all the objections and or rejection.

Claims 1, 9, 12-22, 28-30 and 33-39 are rejected under 35 U.S.C. § 102(b)

The Action rejects claims 1, 9, 12-22, 28-30 and 33-39 under 35 U.S.C. § 102(b) as being anticipated by Davis, et al., U.S. Patent Application No. US2003/0049318 (here after referred to as Davis), which is said to disclose the claimed invention. Applicants assert that Davis fails to meet the standard of 35 U.S.C. § 102(b).

Specifically, Davis does not teach each and every limitation of the present invention. Davis teaches a drug product having two portions both of which contain guaifenesin. The first portion includes a first quantity of guaifenesin in an immediate release formulation and a second portion including a second quantity of guaifenesin and at least one additional drug ingredient release-delaying matrix. In addition, Davis does not teach the first and the second active are disposed on separate carriers. In paragraph [0054] of Davis, the additional drug ingredient diffuses from a gel when exposed to media of low pH.

> [0054] Additionally, when at least one additional drug ingredient is present in the combination of hydrophilic and water-insoluble polymers of the sustained release formulation of the present invention, the additional drug ingredient diffuses from the gel

> when the combination gels when exposed to media of low pH. As discussed above, when the gelled polymer combination is exposed to media of a higher pH, the gel begins to slowly dissolve thereby releasing at least one additional drug ingredient at a controlled rate in addition to the guaifenesin.

Davis does not provide that the first and the second active are disposed on separate carriers or that the second active is disposed on a separate carrier in three or more layers. Davis fails to meet the standard of 35 U.S.C. 102(b) namely, teaching all elements of the claimed invention either explicitly or impliedly. Applicants respectfully submit that claims 1, 9, 12-22, 28-30 and 33-39 are not anticipated by Davis and respectfully request the Examiner withdraw the rejection under 35 U.S.C. §102.

Claims 1, 4, 9, 11 and 18 are rejected under 35 U.S.C. § 102(b)

The Action also rejects claims 1, 9, 12-22, 28-30 and 33-39 under 35 U.S.C. § 102(b) as being anticipated by Blume, et al., U.S. Patent No. 6,372,252 (here after referred to as Blume), which is said to disclose the claimed invention. Applicants assert that Blame fails to meet the standard of 35 U.S.C. § 102(b).

Blume does not disclose an enveloped pharmaceutical composition having a first active available for immediate release and a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein the first and the second active are disposed on separate carriers, with the second active having three or more layers of the second active agent. In fact, Blume does not disclose a second active agent. Blume teaches a modified release tablet having two portions, wherein a first portion includes a first quantity of guaifenesin in an immediate release form that becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin and a release-delaying matrix comprising a hydrophilic polymer and a water-insoluble polymer. Blume does not teach an immediate release first active and an extended release second active disposed on separate carriers.

Blume merely discloses a tablet having two portions with each portion containing guaifenesin. Blume discloses a bi-layer tablet that maintains serum concentration levels of guaifenesin at a therapeutically effective level for at least a twelve hour period without an

increase in the drug strength of the dosage form. Blume does not teach, an enveloped pharmaceutical composition having a first active available for immediate release and a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an antitussive and mixtures thereof, wherein the first and the second active are disposed on separate carriers, wherein the second active comprises three or more layers of the second active agent.

Blume does not provide that the first and the second active are disposed on separate carriers or that the second active is disposed on a separate carrier in three or more layers. Davis fails to meet the standard of 35 U.S.C. 102(b) namely, teaching all elements of the claimed invention either explicitly or impliedly. Applicants respectfully submit that claims of the present invention are not anticipated by Blume and respectfully request the withdrawal of the rejection under 35 U.S.C. §102.

Claim Rejections – Claims 1 and 4-61 are rejected under 35 U.S.C. § 103(a)

The Action also rejects claims 1 and 4-61 under 35 U.S.C. § 103(a) as being unpatentable over Devane, et al., U.S. Patent No. 6,228,398 (here after referred to as Devane), in view of Dang, et al., U.S. Patent No. 6,462,094 (here after referred to as Dang) and Davis.

The Action attempts to combine Devane with Dang and Davis to establish a prima facie case of obviousness. However, the Action fails on all counts, as there is no suggestion or motivation in the prior art to modify the reference or to combine reference teachings as proposed; there is no reasonable expectation of success; and the combined references do not teach or suggest all the claim limitations. MPEP § 2143; *In re Vacek*, 947 F.2d 488 (Fed. Cir. 1991).

Devane provides a composition that is delivered in a modified release; however the composition in operation delivers an active ingredient in a pulsed manner. The Devane composition is released to deliver a plasma profile substantially similar to the plasma profile produced by the administration of two or more immediate release dosage forms given sequentially. Devane does not provide a first active available for immediate release and a second active for extended release. Devane includes a first active released immediately upon administration and a second portion of the active ingredient is released rapidly after an initial delay period. Regardless of what the active ingredients are, Devane

merely provides sequentially immediate release dosage and not an extended release, see col. 3, ll. 32-67:

> Accordingly, it is an object of the present invention to provide a multiparticulate modified release composition containing an active ingredient which in operation produces a plasma profile substantially similar to the plasma profile produced by the administration of two or more IR dosage forms given sequentially.
> It is a further object of the invention to provide a multiparticulate modified release composition which in operation delivers an active ingredient in a pulsatile manner.
> Another object of the invention is to provide a multiparticulate modified release composition which substantially mimics the pharmacological and therapeutic effects produced by the administration of two or more IR dosage forms given sequentially.
> Another object of the invention is to provide a multiparticulate modified release composition in which a first portion of the active ingredient is released immediately upon administration and a second portion of the active ingredient is released rapidly after an initial delay period in a bimodal manner. (emphasis added)

Devane does not provide a first active available for immediate release and a second active for extended release. Devane merely provides a first active released immediately upon administration and a second portion of the active ingredient as a delayed sequentially immediate release dosage. Not only does Devane not teach: an extended release; it does not teach guaifenesin as the first active or phenylephrine as the second active; it does not teach the second active for extended release is selected from the group consisting of a decongestant, an antihistamine, an antitussive and mixtures thereof; and it does not teach the second active can include three or more layers of the second active agent.

Dang teaches a conventional tablet prepared by well known conventional tabletting techniques that includes phenylephrine tannate and guaifenesin. Dang does not teach a first active available for immediate release and a second active for extended release. Dang does not teach extended release or extended delivery in any form, per se, but rather a composition with an immediate expectorant **action** and a prolonged decongestant **action** of phenylephrine tannate (see col. 2, ll 1-32). However, expectorant action and the prolonged decongestant action are just that actions and depend on the subject and on many other factors and therefore may or may not correlate directly to a release profile of an active agent. The present invention provides an enveloped pharmaceutical composition having a first active available for immediate release and a second active for extended release with the first and the second actives disposed on separate carriers. In contrast, Dang only teaches a phenylephrine tannate and guaifenesin in a conventional tablet. Dang in no way provides: a first active available for immediate release and a second active for extended release selected from

the group consisting of a decongestant, an antihistamine, an antitussive and mixtures thereof; nor does Dang teach the first and the second active are disposed on separate carriers; nor does Dang teach the second active having three or more layers of the second active agent.

As stated above, and incorporated here in its entirety, Davis teaches a drug product having two portions both of which contain guaifenesin. Davis teaches a compressed bi-layer tablet with an immediate release formulation of guaifenesin and a delayed release matrix formulation of guaifenesin, Davis does not teach an enveloped formulation that combines a first active on a carrier and a second active on a carrier. The delayed release matrix formulation of Davis is simply a media that when exposed to low pH forms a gel from which the guaifenesin diffuses. Davis does not teach each and every limitation of the present invention.

The Applicants disagree with the Action's assertion that Devane provides the "means," and Dang and Davis the modivation. To the contrary, Devane teaches nothing more than an immediate release and a delayed immediate release and nothing in Devane teaches an extended release. The addition of Dang and Davis fail to cure this deficiency and fail to provide a composition having a first active available for immediate release and a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an antitussive and mixtures thereof, with the first and the second active are disposed on separate carriers.

The Action relies on the fact that the elements of the present invention can supposedly be found in the combination of references as the basis for finding both the motivation and suggestion to combine them. The Federal Circuit has consistently held that "…the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the same manner claimed" (emphasis added) *In re Rouffet* 149 F.3d 1350, 1357 (Fed. Cir. 1998). Therefore, the Examiner is asked to state on the record the particular reasons the skilled artisan, would have selected these components for combination *in the manner claimed*, namely, the a first active available for immediate release and a second active for extended release with the first and the second active are disposed on separate carriers.

Even if there was a suggestion or motivation in the prior art to modify the reference and a reasonable expectation of success (which there clearly are not), obviousness would still not be

found as the combined references do not suggest all the claim limitations of the present invention. The combination of Devane with Dang and Davis fail to provide each and every limitation of the present invention. The combined references do not teach an enveloped pharmaceutical composition having a first active available for immediate release and a second active for extended release and the first and the second active are disposed on separate carriers.

Accordingly, Applicants respectfully submit that claims 1 and 4-61 are not obvious over Devane, Dang and Davis, therefore, allowable under 35 U.S.C. § 103(a). For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion

Accordingly, after entry of this Amendment, the claims numbering has been corrected, original Claims 1 and 4-61 are pending in the above-identified Application. Withdrawal of the objections and rejections and an early Notice of Allowance are earnestly requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

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Respectfully submitted,

Chainey Singleton
Reg. No. 53,598
ATTORNEY FOR APPLICANTS

Customer No. 34,725
Chalker Flores, LLP
2711 LBJ FRWY, Ste. 1036
Dallas, TX 75234
214.866.0001 Telephone
214.866.0010 Facsimile